



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/810,196	05/11/97	QUEEN	11823-806710

WILLIAM M SMITH
TOWNSEND AND TOWNSEN AND CREW
8TH FLOOR
TWO EMBARCADERO CENTER
SAN FRANCISCO CA 94111-3834

HM11/0503

EXAMINER

NOLAN, F

ART UNIT

PAPER NUMBER

1544

DATE MAILED:

05/03/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Interview Summary

Application No.
08/571,802

Applicant(s)

Ishii

Examiner

Michael Pak

Group Art Unit

1646



All participants (applicant, applicant's representative, PTO personnel):

(1) Michael Pak (Ex.)

(3) _____

(2) Janelle Waack (Att)

(4) _____

Date of Interview Apr 29, 1999

Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description:

Agreement ☐ was reached. ☒ was not reached.

Claim(s) discussed: pending

Identification of prior art discussed:

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Examiner will remove the finality of the last office action and will send a non-final action shortly.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

1. ☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☐ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Michael D. Pak

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. The amendment filed 22 December 1995 (paper No. 9) and filed 16 April 1998 (paper No. 12) have been entered.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office actions.
4. The Declaration under 37 CFR 1.132 filed 5 November 1998 (Paper No. 16) is sufficient to overcome the rejection of claims based upon 35 U.S.C. 112 paragraph 1.

Claim Rejections - 35 USC § 102

5. Claims 24-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Lewis et al. (A1) for the reasons set forth in the past office actions (Paper Nos. 5 and 8) and further discussed forth below.

Newly submitted claims 46-56 encompass a method of treating locus ceruleus neurons with IGFs. Lewis et al. teach method of treatment for diseases such as Alzheimer's disease, stroke, epilepsy, amyotrophic lateral sclerosis, or Parkinson's disease

by administering an effective amount of IGF I or IGF II or a combination thereof. Diseases such as stroke and Parkinson's disease affect the locus ceruleus neurons. Thus, the treatment by the parenteral administration of IGF I or IGF II to treat these diseases comprise a nonintracranial administration of an IGF in an amount to effective to treat the locus ceruleus neurons.

Newly submitted claims 57-67 encompass a method of treating the central nervous system. The scope of the claims are the same as previously rejected claims where the claims are directed to a method of treating the central nervous system.

Applicants argue that the reference teaches away from the claimed invention for IGF acting across the blood-brain barrier by characterizing the blood brain barrier as a problem. However, Lewis et al. teach the method of parenteral administration of IGF-I or IGF-II with specific dosage ranges of 1ug/kg/day to 1 g/kg/day as well as ranges 0.01 mg/kg/day to 100mg/kg/day (column 10, lines 3-22). Furthermore, IGF I and II inherently cross the blood brain barrier. It should be noted that Lewis et al. teaches both parenteral administration and the blood brain barrier problem and the invention of parenteral administration anticipates the claims. Applicant's citations of "Monarch Knitting Mach. v. Sulzer Morat GMBH" and "Dow Chemical Co. v. American Cyanamid Co." are not applicable to this application

because the case laws holdings are directed to 35 U.S.C. 103 obviousness rejection while the present rejection is directed to 35 U.S.C. 102.

6. Claims 40 and 42 are rejected under 35 U.S.C. 102(a) as being anticipated by Gluckman et al. ((A62); BBRC, 1992).

Gluckman et al. teach a method of administering 20-200 ug of IGF I to a rat which results in decreased loss of neuronal cells in a hypoxic-ischemic insult model (page 595, first full paragraph; figure 2; page 598).

Claims encompass increasing the circulating concentration limitation which the examiner takes the position to mean diffusion of the administered material without an art accepted definition in the specification. The concentration administered by Gluckman et al. is in the range of claim 42 limitation.

7. Claims 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Aroonsakul (A51); U.S. 4,898,856).

Aroonsakul teach a method of administering steroids and hormones to increase the concentration of IGF I in the bloodstream of human patients (columns 1-2; figures 1-4).

The claims encompass indirect increase in bloodstream of IGF I because of the limitation "increasing the circulating concentration".

Serial Number: 08/571,802
Art Unit: 1646

4

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Pak whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak
Patent Examiner
Art Unit 1646
29 April 1999


PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER